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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,204	03/06/2001	Ronald Brown Miller	222.94213.CON2	1587

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EXAMINER

BARTS, SAMUEL A

ART UNIT PAPER NUMBER

1621

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,204

Applicant(s)

MILLER ET AL.

Examiner

Samuel A Barts

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 20-41 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 21-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed October 29, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments

2. Applicant's arguments filed October 29, 2002 have been fully considered but they are not persuasive.

Argument 1: The references are not properly combinable. Applicant argues that the Raffa et al reference fails to contemplate a controlled release oral dosage form. Applicant further adds that the Bondi reference teaches controlled release oral dosage forms but recites tramadol among a laundry list of other pharmaceuticals. Applicant then concludes that there would be no motivated to combine these references.

Examiner Response: The Raffa et al reference of course did not teach controlled released dosage, because if it did the reference would have anticipated the claimed invention. Therefore, the real question is whether one of ordinary skill in the art having a compound with a pharmaceutical property would be motivated to look for a controlled method of administering said pharmaceutical.

The administering of pharmaceutical via a controlled means is fundamental. Even the general public is exceedingly aware of a time factor when taking medicines from antihistamines, cold medicaments and even vitamins. A skilled artisan is aware of making compositions that produce these time factors for medicines. Hence, once a compound has been recognized as having a beneficial pharmaceutical property, one of ordinary skill in the art would look for methods of controlled release of that pharmaceutical. Since, the secondary reference of Bondi recites controlled release methods and list tramadol one would be motivated to use the teaching of Bondi. The fact that a large laundry list of compounds is recited does not minimize the teaching of this reference. In fact it actually strengthens the suggestion that controlled release methods are well known and that they can be used for a wide variety of pharmaceuticals. Which is the position the Examiner has taken.

Argument 2: Applicant puts forth the position that even if the combination is proper there is no suggestion of making a dosage form for at least about 12 hours or 24 hours.

Examiner Response: The dosage form of medicaments is extremely well known. Again even the general public is aware of taking medicaments based on how long they will last. Therefore, one of ordinary skill in the art would be motivated

to modify the dosage form to standard time frames. 4, 8, 12 and 24 hrs are recognized standard time frames for pharmaceuticals. A 24 hrs dosage form simply means once a day. A 12 hrs dosage form means twice a day.

The rejection is being maintained.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1 and 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al in view of Bondi. For reasons see previous office action and above arguments.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 703-308-4630. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Samuel A Barts
Primary Examiner
Art Unit 1621

s.b.
January 12, 2003